Georgia Department of Natural Resources
Environmental Protection Division • Air Protection Branch
4244 International Parkway • Suite 120 • Atlanta • Georgia 30354
404/363-7000 • Fax: 404/363-7100
Chris Clark, Commissioner
F. Allen Barnes, Director

NARRATIVE

TO: David Matos DMM
FROM: Amy Young AY
DATE: March 19, 2010

Facility Name:	**Bard Medical Division, Covington**
AIRS No.:	21700021
Location:	Covington, Georgia (Newton County)
Application #:	18737 and 19408
Date of Application:	January 20, 2009 (Application # 18737) and December 30, 2009 (Application # 19408

Background Information

Bard Medical Division, Covington located in Covington, Georgia in Newton County, produces sterilized silicone catheters for use in the medical industry. The sterilization of the catheters takes place in one of four sterilization vessels. An additional sterilization vessel is proposed in Application No. 19408. The packaged catheters are placed on pallets in the sterilization vessel. The vessel is then charged with ethylene oxide. The gas permeates the packages during the cycle. At the completion of the cycle, the vessel is evacuated and backfilled with airwash. The evacuated gas is vented to the regenerative thermal oxidizer (Control ID. No. RTO-1). The pallets are then placed in one of four primary aeration cells. In the aeration cells, the residual ethylene oxide dissipates and is evacuated to the regenerative thermal oxidizer (RTO-1) unit. The residence time for the pallets is 24 hours, and they are then moved to the secondary aeration cells. Any residual ethylene oxide continues to dissipate and is vented to the regenerative thermal oxidizer (RTO-1) unit before shipping. Two additional aeration cells are proposed in Application No. 19408.

Purpose of Application

Bard Medical Division, Covington submitted a Title V Renewal application (Application No. 18737) dated January 20, 2009. Within the cover letter, the facility requested permitting as a Synthetic Minor Source. The facility's maximum controlled emissions are less than the major source threshold and they can be permitted as a synthetic minor source. In addition, the facility updated their application and submitted a SIP application (Application No. 19408) on December 30, 2009 which is being processed concurrently with their new Synthetic Minor permit. This application is for the construction of one new Sterilization Vessel and two new Aeration Cells. Emissions from the new units do not impact the facility's ability to become a Synthetic Minor Source.

It should be noted that the facility is not required to have a Title V permit due to applicability of 40 CFR 63 Subpart O – "Ethylene Oxide Emission Standards for Sterilization Facilities" per 40 CFR 63.360(f). The following language was added to the regulation on December 19, 2005:

> If you are an owner or operator of an area source subject to this subpart, you are exempt from the obligation to obtain a permit under 40 CFR part 70 or 71, provided you are not required to obtain a permit under 40 CFR 70.3(a) or 71.3(a) for a reason other than your status as an area source under this subpart. Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart applicable to area sources.

Updated Equipment List

Emission Units			Associated Control Devices	
Source Code	Description	Installation Date	Source Code	Description
SV1	Sterilization Vessel # 1	1991	RTO-1	Regenerative Thermal Oxidizer
SV2	Sterilization Vessel # 2	1991	RTO-1	Regenerative Thermal Oxidizer
SV3	Sterilization Vessel # 3	1991	RTO-1	Regenerative Thermal Oxidizer
SV4	Sterilization Vessel # 4	1991	RTO-1	Regenerative Thermal Oxidizer
SV5	Sterilization Vessel # 5	Future	RTO-1	Regenerative Thermal Oxidizer
A1A	Aeration Cell 1A	1991	RTO-1	Regenerative Thermal Oxidizer
A2A	Aeration Cell 2A	1991	RTO-1	Regenerative Thermal Oxidizer
A3A	Aeration Cell 3A	1991	RTO-1	Regenerative Thermal Oxidizer
A4A	Aeration Cell 4A	1991	RTO-1	Regenerative Thermal Oxidizer
A5A	Aeration Cell 5A	Future	RTO-1	Regenerative Thermal Oxidizer
A1B	Aeration Cell 1B	1991	RTO-1	Regenerative Thermal Oxidizer
A2B	Aeration Cell 2B	1991	RTO-1	Regenerative Thermal Oxidizer
A3B	Aeration Cell 3B	1991	RTO-1	Regenerative Thermal Oxidizer
A4B	Aeration Cell 4B	1991	RTO-1	Regenerative Thermal Oxidizer
A5B	Aeration Cell 5B	Future	RTO-1	Regenerative Thermal Oxidizer

Fugitive Emission Sources

Source Code	Description
STOR	Product Storage

Emissions Summary

Facility-Wide Emissions
(in tons per year)

Pollutant	Potential Emissions (before modification	Actual Emissions (before modification)	Potential Emissions (after modification)	Actual Emissions (after modification)
	TPY	TPY		
PM	2.13	2.13	2.13	2.13
NOx	36.88	36.88	36.88	36.88
SO_2	2.03	2.03	2.03	2.03
CO	26.98	26.98	26.98	26.98
VOC	5.55	5.55	6.79	6.79
Max. Individual HAP (Ethylene Oxide)	3.9	3.9	5	5
Total HAP*	3.96	3.96	5.06	5.06

* includes HAPs from combustion units

Ethylene Oxide emissions were based on mass balance calculations. Emissions of PM, NOx, SO2, CO, and VOC were based on AP-42 factors for small boilers (Chapter 1.4) , AP-42 factors for large diesel engines (Chapter 3.4), and AP-42 factors for natural gas engines (Chapter 3.2). For the emergency generators, 500 hrs/yr of operation were assumed. For the natural gas fired emergency generators, worst case factors from 2 stroke lean burn, 4 stroke lean burn, and 4 stroke rich burn were selected.

Regulatory Applicability

Sterilization Equipment including Sterilization Vessels and Aeration Cells

40 CFR 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities
40 CFR 63 Subpart A – General Provisions

The sterilization equipment, including Sterilization Vessels and Aeration Cells (existing and proposed) are subject to 40 CFR 63 Subpart O, which applies to both major and area sources and has a compliance date of December 6, 1998 except for new equipment which shall comply immediately upon startup. Because the facility's usage of Ethylene Oxide is 10 tons or greater, the facility is subject to both the Sterilization chamber vent standard and the aeration room vent standard.

Equipment Exempt from Permitting

The facility operates 72 fuel burning emission units with a rated heat input capacity of 1 million Btu/hr or less burning natural gas. Refer to the application for further details on these sources. All of these sources are exempt from permitting under the provisions of Georgia Rule 391-3-1-.03(6)(b)(3):

3. Any fuel-burning equipment with a rated input capacity of 2.5 million BTUs per hour or less.

The facility has 4 boilers which burn natural gas, two (2) rated at 6.276 MMBtu/hr each and two (2) rated at 4.186 MMBtu/hr. The RTO has two(2) burners which burn natural gas which are rated at 7.5 MMBtu/hr each. The facility also has fuel burning equipment that includes three natural gas fired units rated at 1.6 MMBtu/hr, 4.375 MMBtu/hr, and 4.375 MMBtu/hr. All units are exempt from permitting under the provisions of Georgia Rule 391-3-1-.03(6)(b)(1)

1. Fuel-burning equipment having a total heat input capacity of less than 10 million BTUs per hour burning only natural gas, LPG and/or distillate fuel oil containing 0.50% sulfur by weight or less.

The facility operates 2 units exempt from permitting under 391-3-1-.03(6)(h)(3)(v) –Bakery ovens and confection cookers. Refer to Application No. 18737.

The plant operates laboratory and R&D facilities. The operations are exempt from permitting under Georgia Rule 391-3-1-.03(6)(f)(1).

The plant operates equipment for the compression, molding, injection, and extrusion of plastics. This equipment is exempt from permitting under Georgia Rules 391-3-1-.03(6)(h)(5) and (13).

The facility operates two tanks that are exempt from permitting under Georgia Rules 391-3-1-.03(6)(c)(1) and (2)

The facility operates 4 stationary engines used for emergency power generation. The diesel fired emergency generator is 1865 HP. The 3 natural gas fired emergency generators are 2.3 MMBtu/hr total. This equipment is exempt from permitting under Georgia Rules 391-3-1-.03 (b)(11)(i).

The facility operates 2 stationary gasoline engines with combined hp < 225 Hp and operating < 1000 hr/yr each. One 18 hp engine is used approximately 12 hrs/year for repair work and One 9 hp engine used approximately 20 hrs/year for miscellaneous cleaning activities. These units are exempt from permitting under 393-3-1-.03(b)(11)(iv)

The facility has 20 portable drums and/or barrels < 550 gal each that are exempt from permitting under 391-3-1-.03(6)(c) (7)

The facility has brazing, soldering, and welding equipment which is exempt from permitting under 391-3-1-.03(6)(e) (3)

Permit Conditions

The permit conditions for Bard Medical Division, Covington are described below. In many cases, the conditions were carried over from the Title V permit No. 3841-217-0021-V-02-0.

Section 1 contains general requirements applicable to all SIP facilities.

Conditions 2.1 and 2.2 specify the applicability of 40 CFR 63 Subpart O and Subpart A to the facility.

Condition 2.3 requires the reduction of ethylene oxide emissions from each sterilizer chamber vent by at least 99% in accordance with 40 CFR 63.362(c). This Condition also ensures along with Condition No. 2.4 that the Title V major source thresholds for HAP and VOC are not exceeded.

Condition 2.4 requires the reduction of ethylene oxide emissions from each aeration room vent to 1 ppm by volume or less or at least by 99% in accordance with 40 CFR 63.632(d). This Condition also ensures along with Condition No. 2.3 that the Title V major source thresholds for HAP and VOC are not exceeded.

Condition 2.5 states the emission limits on ethylene oxide apply during sterilization operation and not during periods of malfunction in accordance with 40 CFR 63.632(b).

Condition 2.6 contains deadlines by which equipment must comply with 40 CFR 63 Subpart O emission limitations. All existing equipment is expected to already be complying so the Condition is intended primarily for purposes of the proposed equipment (Sterilization Chamber # 5, Aeration Cell 5A, and Aeration Cell 5B).

Condition 3.1 is a general condition for the management of fugitive emissions.

Condition 4.1 specifies the minimum oxidation temperature limit (1447 degrees F) for the Regenerative Thermal Oxidizer (RTO-1) in accordance with 40 CFR 63.363(b)(3) and 63.363(f) and defines an operating parameter deviation as any 24 hour average of the oxidation temperature that is below 1447 degrees F. This temperature was approved by EPD in a letter dated September 22, 1999. In addition, the Condition includes language that would allow a new oxidation temperature limit to be established through testing and that could replace the current temperature limit without permit revision provided written approval from the Division is obtained. Finally, the Condition includes the requirement that the new temperature must be at least equal to or greater than the recommended minimum oxidation temperature recommended by the manufacturer consistent with the language in 40 CFR 63.363(b)(3). A change to the original temperature limit was requested and granted for the CR Bard Madison, GA sterilization facility. In the event that Bard Medical Division, Covington requests a similar change, this condition would provide the flexibility needed to avoid revising the permit.

Condition 4.2, Condition 4.3, and Condition 4.4 are general requirements for control equipment.

Conditions 5.1 require the facility to either monitor and record the oxidation temperature using a continuous temperature monitor or to measure and record Ethylene Oxide concentration in accordance with 63.364(e).

Condition 5.2 requires the monitoring and recording of the oxidization temperature on RTO-1 and contains the accuracy of the temperature monitor consistent with 40 CFR 63.364(c)(4). In a letter dated May 14, 1999 EPD granted the facility permission to demonstrate compliance with §63.364 using the average temperature reading from three temperature monitors located in the combustion chambers of the Regenerative Thermal Oxidizer (RTO-1) as opposed to monitoring temperature at the exhaust point for

the oxidizer. EPD determined that this did not require an alternative monitoring determination from the US EPA Region IV.

Condition 5.3 contains the requirements from 40 CFR 63.364(c)(4) for verifying the accuracy of the temperature monitor.

Conditions 5.4 and 5.5 contain general requirements for the operation and maintenance of monitoring systems.

Condition 6.1 contains the general requirements for conducting performance tests required by the Division.

Condition 6.2 and 6.3 contain a requirement for a performance test for the proposed Sterilization Vessel # 5 and Aeration Cells 5A and 5B to be conducted in accordance with Subpart O. Condition 6.4, 6.5, and 6.6 contain specific test requirements for Subpart O required tests. Condition 6.7 and 6.8 contains test plan and test results submittal requirements for Subpart O.

Conditions 7.1 through 7.3 are general record keeping and reporting requirements.

Condition 7.4 requires the facility to use the continuous temperature data for the Regenerative Thermal Oxidizer to calculate a daily average temperature. The daily data is used to determine compliance with the provisions of 40 CFR 63 Subpart O.

Conditions 7.5, 7.6 and 7.7 are general conditions for 40 CFR 63 Subpart O that require the facility to maintain records and submit reports for monitoring systems and deviations associated with the Regenerative Thermal Oxidizer.

Condition 7.8 is a general condition that requires the facility to submit semiannual reports for the operation of the facility. Most of the required information pertains to deviations and monitor downtime.

Condition 7.9 are the notification requirements for the construction of proposed Sterilization Vessel # 5, Aeration Cell 5A, and Aeration Cell 5B in accordance with Subpart O and the Department's notification requirements.

Conditions 8.1 and 8.2 are general conditions for all synthetic minor sources.

Condition 8.3 revokes the Title V permit currently held by the facility.

Toxic Impact Assessment

An updated TIA for Ethylene Oxide from the entire facility was performed due to higher emissions, new equipment and fugitive emissions not previously modeled. The results of the ISCS3T3 (BEEST for Windows version 9.47) modeling showed that the emissions of Ethylene Oxide will comply with GA EPD's AACs. A copy of the disc with the modeling output file is in the facility's file. A copy of EPD's modeling memo is attached to this narrative.

Summary & Recommendations

Bard Medical Division, Covington will be reclassified as a synthetic minor (SM) source. The facility remains subject to 40 CFR Part 63, Subpart O. It is recommended that a Synthetic Minor permit, Air Quality Permit No. 3841-217-0021-S-03-0 be issued and the existing Air Quality Permit **3841-217-0021-V-02-0** be revoked. Compliance responsibility for the source will remain with SSCP due to the applicability of 40 CFR 63 Subpart O. A public advisory was not deemed necessary for construction of the new sterilization chamber and two new aeration cells.

Table B-1. Stack Parameters

Source	Type	Release Height[1,2] (ft)	(m)	Stack Inside Diameter[1,2] (ft)	(m)	Stack Exit Velocity[3] (ft/s)	(m/s)	Stack Exit Flowrate[1,2] (ft^3/min)	(m^3/s)	Stack Exit Gas Temp[4,5] (°F)	(K)	Ethylene Oxide Emissions[6,7] (lb/yr)	(tpy)	(g/s)
Exhaust Fan EF-17	Point	30	9.15	2.50	0.76	34.0	10.35	10,000	4.72	70	294.26	231.34	0.12	3.33E-03
Exhaust Fan EF-18	Point	30	9.15	2.50	0.76	34.0	10.35	10,000	4.72	70	294.26	231.34	0.12	3.33E-03
Exhaust Fan EF-20	Point	30	9.15	2.50	0.76	34.0	10.35	10,000	4.72	70	294.26	231.34	0.12	3.33E-03
Exhaust Fan EF-21	Point	30	9.15	2.50	0.76	34.0	10.35	10,000	4.72	70	294.26	231.34	0.12	3.33E-03
Exhaust Fan EF-22	Point	30	9.15	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
Exhaust Fan EF-23	Point	25	7.62	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
Exhaust Fan EF-24	Point	25	7.62	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
Exhaust Fan EF-25	Point	25	7.62	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
Exhaust Fan EF-26	Point	25	7.62	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
Exhaust Fan EF-27	Point	25	7.62	3.67	1.12	37.9	11.55	24,000	11.33	70	294.26	555.22	0.28	7.99E-03
RTO	Point	50	15.24	4.00	1.22	30.5	9.30	23,000	10.86	440	499.80	5,815.70	2.91	8.36E-02

1. Exhaust fans' release heights, diameters and flow rates provided in WP Fans.pdf provided via email from John LaMontagne (CR Bard) to Katherine Scott (Trinity) on December 8, 2009.
2. RTO stack height, diameter, flowrate provided via email from John LaMontagne (CR Bard) to Katherine Scott (Trinity) on December 10, 2009.
3. The stacks' exit velocities were calculated using the stacks' flowrates and areas.
4. The RTO temperature from Georgia EPD response to Application No. 9481 provided via email from John LaMontagne (CR Bard) to Katherine Scott (Trinity) on December 8, 2009.
5. Assumed the exhaust fans operate at ambient temperature.
6. Emissions were provided in COV PTE Mass Balance.pdf provided via email from John LaMontagne (CR Bard) to Katherine Scott (Trinity) on December 8, 2009.
7. The emissions from the exhaust fans are equal the the total fugitive ethylene oxide released from the product, transfer from aeration, and miscellaneous fugitives: 4,256.70 lb/year proportioned by fan size.

Table B-2. Acceptable Ambient Concentrations

Pollutant	CAS No.	Formula	Mol. Wt. (g mol^{-1})	OSHA TWA[1,2] (mg/m3)	Known Carcinogen?[3]	Safety Factor	24-hour AAC[4] (ug/m3)	STEL or C[1] (ppm)	STEL or C[2] (mg/m^3)	15-minute AAC[5] ($\mu g/m^3$)
Ethylene Oxide	75-21-8	C_2H_4O	44.05	1.8	Probable	100	4.28	5.0	9.0	899.03

1. OSHA TWA and STEL from *NIOSH Pocket Guide for Hazardous Chemicals* <http://www.cdc.gov/niosh/npg/npgd0275.html> and 29 CFR 1910.1047, Ethylene oxide.
2. Conversion from ppm to mg/m3 using formula C (mg/m3) = C (ppm) x (MW) ÷ 24.45, per page 11 of *Guideline For Ambient Impact Assessment of Toxic Air Pollutant Emissions.*
3. Weight-of-evidence from EPA's Technology Transfer Network Air Toxics Website *Ethylene Oxide Hazard Summary*, revised January 2000 <http://www.epa.gov/ttn/atw/hlthef/ethylene.html>.
4. The 24-hr AAC is adjusted based on 168 hours per week of potential exposure and the safety factor per the *Guideline* Section III.2.B and III.3.B, respectively.
5. The 15-minute AAC adjusted using the safety factor recommended for acute sensory irritants per the *Guideline* Section III.3.B.

Table B-3. ISC Modeling Results

Year	Max 24-Hour Concentration (µg/m3)	24-Hour AAC (µg/m3)	24-Hour AAC Exceeded?	Max Hourly Concentration ($\mu g/m^3$)	Max 15-min Concentration ($\mu g/m^3$)	15-minute AAC ($\mu g/m^3$)	Short-term AAC Exceeded?
1989	3.44	4.28	No	15.54	20.51	899	No
1990	3.06	4.28	No	15.91	21.01	899	No
1991	3.30	4.28	No	20.71	27.34	899	No
1992	3.53	4.28	No	20.78	27.43	899	No
1993	4.16	4.28	No	16.17	21.35	899	No

Georgia Department of Natural Resources
Environmental Protection Division • Air Protection Branch
4244 International Parkway • Suite 120 • Atlanta • Georgia 30354
404/363-7000 • Fax: 404/363-7100
Noel Holcomb, Commissioner
Carol A. Couch, Ph.D., Director

PF

January 28, 2009

Mr. John LaMontagne
Manager, Facility Engineering
C.R. Bard, Incorporated
8195 Industrial Blvd.
Covington, GA 30014

Re: Application Type: TV, No. 18737, dated January 20, 2009
C.R. Bard, Incorporated, Covington, AIRS No.: 21700021

Dear Mr. LaMontagne:

This is to acknowledge receipt of your Air Quality Permit application. After our initial review of the information and technical data in this application, we will notify you if more information is needed to complete the application so that we can finish our review.

If your company qualifies as a small business (generally those with less than 100 employees), you may contact our Small Business Technical Assistance Program at 404/362-4842 for free and confidential permitting assistance.

To track the status of the air quality permit application, log on to Georgia Environmental Protection Division's *Georgia Environmental Connections Online* (GECO) at the web address http://airpermit.dnr.state.ga.us (registration required) and follow the online instructions.

If you have any questions or concerns regarding your application, please contact me at (404) 362-4844 or via e-mail at amy.young@dnr.state.ga.us. Any written correspondence should reference the above application number that has been assigned to this application and the facility's AIRS number.

Sincerely,

Amy Young

Amy Young
Environmental Engineer
Stationary Source Permitting Program

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209-2695

BARD

January 20, 2009

Georgia Department of Natural Resources
Environmental Protection Division
Air Protection Branch
4244 International Parkway, Suite 120
Atlanta, Georgia 30354-3908

To Whom it May Concern:

Enclosed are two copies (on CD) of our Title V Permit Renewal Application for our Facility located in Covington Georgia.

As part of this renewal process we are also requesting that the Facility be permitted as a Synthetic Minor source.

If you have any questions regarding this information, please contact me at (770) 784-6186.

Sincerely,

John LaMontagne
Process Technology Engineer
Bard Medical Division
C.R. Bard Incorporated

cc: B. Bruette

480-06

State of Georgia
Department of Natural Resources
Environmental Protection Division
Air Protection Branch
Major Source Operating Permit Application

4244 International Parkway
Suite 120
Atlanta, Georgia 30354-3906
404-363-7000

Certifications and Signatures

Facility Name: CR Bard Inc Urological Div

Project Name: 2009 Covington Renewal Application

AIRS Number: 132170021

Submittal File Name: 132170021_20090120.mdb

COMPUTER DISK VIRUS EXAMINATION CERTIFICATION:
I certify that, to the best of my knowledge, the completed electronic application disk has been inspected and found free of any known viruses.

Signature: _____ Date: 1/20/09

Name (print): John LaMontagne

Offical Title: Process Technology Engineer

SOFTWARE USAGE CERTIFICATION:
I certify that the software used to complete the Georgia Title V application was used as provided by the Georgia Environmental Protection Division, Air Protection Branch and was unaltered in any way. I understand that the submission of a Title V (Part 70) application completed using any altered version of the provided software constitutes the submission of an incomplete application and that such action may be subject to enforcement by the Georgia Air Protection Branch and/or the US EPA.

CERTIFICATION OF COMPLIANCE:
Except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, I hereby certify that this facility is in compliance with all applicable requirements effective as of the date of this certification and will continue to comply with such requirements. For applicable requirements promulgated as of the date of this certification, that will become effective during the permit term, I further certify that, except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, this facility will comply with such requirements and will continue to comply with such requirements.

I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this application and all of its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment.

Unless otherwise required by the Director, compliance certifications will be submitted to the Director at least annually.

SIGNATURE OF RESPONSIBLE OFFICIAL:

Signature: _____ for M. Mayo Date: Jan 20, 2009

Name (print): Brian R. Dumbleton

Offical Title: Director, Quality Assurance

Address: 8195 Industrial Blvd.
Covington, GA 30014

Notary Public Certification of Responsible Official's Signature:

Signature of Notary Public: _____

TINA H. MARSHBURN
Notary Public, Henry County, Georgia
My Commission Expires October 25, 2009

State of [redacted]
Department of Natural Resources
Environmental Protection Division
Air Protection Branch
Major Source Operating Permit Application

RECEIVED

JAN 21 2009

18737

AIR PROTECTION BRANCH

4244 International Parkway
Suite 120
Atlanta, Georgia 30354-3906
404-363-7000

Certifications and Signatures

Facility Name: CR Bard Inc Urological Div

Project Name: 2009 Covington Renewal Application

AIRS Number: 132170021

Submittal File Name: 132170021_20090120.mdb

COMPUTER DISK VIRUS EXAMINATION CERTIFICATION:
I certify that, to the best of my knowledge, the completed electronic application disk has been inspected and found free of any known viruses.

Signature: [signature] Date: 1/20/09

Name (print): John LaMontagne

Offical Title: Process Technology Engineer

SOFTWARE USAGE CERTIFICATION:
I certify that the software used to complete the Georgia Title V application was used as provided by the Georgia Environmental Protection Division, Air Protection Branch and was unaltered in any way. I understand that the submission of a Title V (Part 70) application completed using any altered version of the provided software constitutes the submission of an incomplete application and that such action may be subject to enforcement by the Georgia Air Protection Branch and/or the US EPA.

CERTIFICATION OF COMPLIANCE:
Except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, I hereby certify that this facility is in compliance with all applicable requirements effective as of the date of this certification and will continue to comply with such requirements. For applicable requirements promulgated as of the date of this certification, that will become effective during the permit term, I further certify that, except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, this facility will comply with such requirements and will continue to comply with such requirements.

I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this application and all of its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment.

Unless otherwise required by the Director, compliance certifications will be submitted to the Director at least annually.

SIGNATURE OF RESPONSIBLE OFFICIAL:

Signature: [signature] for M. Mayo Date: Jan 20, 2009

Name (print): Brian R. Drumheller

Offical Title: Director, Quality Assurance

Address: 8195 Industrial Blvd.
Covington, GA 30014

Notary Public Certification of Responsible Official's Signature:

Signature of Notary Public: Tina H Marshburn

TINA H. MARSHBURN
Notary Public, Henry County, Georgia
My Commission Expires October 25, 2009

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

BARD

December 30, 2009

Amy Young
Georgia Department of Natural Resources
Environmental Protection Division
Air Protection Branch
4244 International Parkway, Suite 120
Atlanta, Georgia 30354-3908

Ms. Young:

Enclosed please find:

- Two copies (on CD) of our revised Title V Permit Renewal Application for our Facility located in Covington Georgia. Information for our proposed additional equipment has been added and minor corrections made.
- Two copies of the SIP application for proposed additional equipment at our Covington Facility.
- Two copies (including 2 CDs) of the Toxic Impact Assessment for our Covington Facility. This assessment includes the proposed additional equipment.
- Revised Summary of Fuel Burning Equipment, including two gasoline engines, per your request.

This information is provided per your request as support for the Permit renewal process and our request to be permitted as a Synthetic Minor source.

If you have any questions regarding this information, please contact me at (770) 784-6186.

Sincerely,

John LaMontagne
Process Technology Engineer
Bard Medical Division
C.R. Bard Incorporated

cc: J. Pertoso

State of Georgia
Department of Natural Resources
Environmental Protection Division
Air Protection Branch
Major Source Operating Permit Application

4244 International Parkway
Suite 120
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404-363-7000

Certifications and Signatures

Facility Name: CR Bard Inc Bard Medicall Div

Project Name: 2009 revised

AIRS Number: 132170021

Submittal File Name: 132170021_20091230.mdb

COMPUTER DISK VIRUS EXAMINATION CERTIFICATION:
I certify that, to the best of my knowledge, the completed electronic application disk has been inspected and found free of any known viruses.

Signature: _____ Date: 12/30/09

Name (print): John LaMontagne

Offical Title: Process Technology Engineer

SOFTWARE USAGE CERTIFICATION:
I certify that the software used to complete the Georgia Title V application was used as provided by the Georgia Environmental Protection Division, Air Protection Branch and was unaltered in any way. I understand that the submission of a Title V (Part 70) application completed using any altered version of the provided software constitutes the submission of an incomplete application and that such action may be subject to enforcement by the Georgia Air Protection Branch and/or the US EPA.

CERTIFICATION OF COMPLIANCE:
Except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, I hereby certify that this facility is in compliance with all applicable requirements effective as of the date of this certification and will continue to comply with such requirements. For applicable requirements promulgated as of the date of this certification, that will become effective during the permit term, I further certify that, except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, this facility will comply with such requirements and will continue to comply with such requirements.

I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this application and all of its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment.

Unless otherwise required by the Director, compliance certifications will be submitted to the Director at least annually.

SIGNATURE OF RESPONSIBLE OFFICIAL:

Signature: _____ for Mary S. Maya Date: 12/30/09

Name (print): Barry R. Dornhelm

Offical Title: Director, Quality Assurance

Address: 8145 Industrial Blvd
Covington, GA 30014

Notary Public Certification of Responsible Official's Signature:

Notary Public, Newton County, Georgia
My Commission Expires Feb. 26, 2011

Signature of Notary Public: _____ Kelly Collins

Printed on: 12/30/09

State of Georgia
Department of Natural Resources
Environmental Protection Division
Air Protection Branch
Major Source Operating Permit Application

4244 International Parkway
Suite 120
Atlanta, Georgia 30354-3906
404-363-7000

Certifications and Signatures

Facility Name: CR Bard Inc Bard Medicall Div

Project Name: 2009 revised

AIRS Number: 132170021

Submittal File Name: 132170021_20091230.mdb

COMPUTER DISK VIRUS EXAMINATION CERTIFICATION:
I certify that, to the best of my knowledge, the completed electronic application disk has been inspected and found free of any known viruses.

Signature: John L. LaMontagne Date: 12/30/09

Name (print): John LaMontagne

Offical Title: Process Technology Engineer

SOFTWARE USAGE CERTIFICATION:
I certify that the software used to complete the Georgia Title V application was used as provided by the Georgia Environmental Protection Division, Air Protection Branch and was unaltered in any way. I understand that the submission of a Title V (Part 70) application completed using any altered version of the provided software constitutes the submission of an incomplete application and that such action may be subject to enforcement by the Georgia Air Protection Branch and/or the US EPA.

CERTIFICATION OF COMPLIANCE:
Except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, I hereby certify that this facility is in compliance with all applicable requirements effective as of the date of this certification and will continue to comply with such requirements. For applicable requirements promulgated as of the date of this certification, that will become effective during the permit term, I further certify that, except as stated on the Compliance Plan For a Non-Compliant Emission Unit or Group form of this application, this facility will comply with such requirements and will continue to comply with such requirements.

I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this application and all of its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment.

Unless otherwise required by the Director, compliance certifications will be submitted to the Director at least annually.

SIGNATURE OF RESPONSIBLE OFFICIAL:

Signature: for Mary S. Mayo Date: 12/30/09

Name (print): Boris R. Dmochowski

Offical Title: Director, Quality Assurance

Address: 8195 Industrial Blvd
Covington, GA 30014

Notary Public Certification of Responsible Official's Signature:

Notary Public, Newton County, Georgia
My Commission Expires Feb. 26, 2011

Signature of Notary Public: Kelly Collins Kelly Collins

Printed on: 12/30/09

From: Amy Young
To: john.lamontagne@crbard.com
Date: 9/11/2009 3:10 PM
Subject: Re: Additional Information Request: C.R. Bard, Incorporated Covington

Mr. LaMontagne,

We request the following information needed to continue with processing of the Synthetic Minor permit application for C.R. Bard, Incorporated Covington.

Please provide the calculations of potential to emit (PTE) for criteria pollutants, individual HAP emissions, and total HAP emissions
from all emitting equipment at the facility, including all fuel burning equipment. Provide detailed calculations that include heat input for each fuel burning unit, emissions factors, mass balance for EO sterilization process, etc.

Please provided the above requested information by October 9, 2009. Feel free to call or email me with any questions or concerns.

Sincerely,

Amy Young
Environmental Engineer
GA Dept. of Natural Resources
EPD Air Protection Branch
Stationary Source Permitting Program
4244 International Pkwy, Suite 120
Atlanta, GA 30354
Phone: 404-362-4844
Fax: 404-363-7100

From: "LaMontagne, John" <John.LaMontagne@crbard.com>
To: "Amy Young" <Amy.Young@dnr.state.ga.us>
CC: "Pertoso, Jason" <Jason.Pertoso@crbard.com>
Date: 10/7/2009 1:52 PM
Subject: CR Bard Response to Request for Additional Information
Attachments: Ques Response Cov Title V Renew 2009 r0.pdf

Amy,

See attached information in response to your 9/11/09 email request.

Please call or email if you have questions or need additional information.

I have included an additional vessel in the PTE calculations as we would like to include this in the permit renewal. Please let me know if this is possible and if so what additional steps we need to take to facilitate this request.

Regards,

John LaMontagne

Process Technology Engineer

Bard Medical Division

770 784 6186 office

770 652 2049 mobile

C.R. Bard Covington Sterilization Air Permit Renewal 2009
Potential to Emit Calculation

Sterilizer @ max capacity 365.0 day per year

Vessel	1	2	3	4	5		
Pallets/run	8	24	24	24	24		
EO/run (lb.)[1]	35	125	125	125	125		
runs/24 hrs[2]	3	3	3	3	3		
lbs/day	105	375	375	375	375		
lbs EO/yr	38325	136875	136875	136875	136875	**585,825**	Total lbs EO/yr
Pal/yr	8760	26280	26280	26280	26280	**113880**	Total Pallets

[1]added to gas wt used per run to be conservative
[2]to estimate worst case use 3 runs per day

PTE Summary (tons)

	NOX	CO	PM	SO2	VOC	HAP
Fuel Burning Nat Gas	23.3	19.57	1.77	0.14	1.28	0
Sterilization Generator[1]	11.19	2.56	0.33	1.89	0.3	0.01
Plant Generators[1]	2.32	2.11	0.03	0	0.07	0.05
Gas Engines[1]	0.07	2.74	0.005	0.004	0.14	0
Process EO	0	0	0	0	5	5
TOTAL	36.88	26.98	2.135	2.034	6.79	5.06

[1]used 500 hrs operation

C.R. Bard Covington Sterilization Air Permit Renewal 2009

C.R. Bard, Covington Ga. Mass Balance Calculations

Assumptions:

Product xfer time from sterilizer to aeration = 5 min. = 0.083300 (hr.)

2 % Product absorption based on Frank Davis memo Subject Ethylene Oxide, 9/25/08

EO will off-gas from products during aeration per equation: $C = Co\ e^{(-kt)}$

Co = EO concentration at tine 0
C = Final EO concentration
k = EO degassing rate constant
t = degassing time in hrs.

k = 0.06151 lb\hr. This is an estimation based on Frank Davis memo Subject Ethylene Oxide, 9/25/08

585825 lbs. total EO usage based on full Maximum operation from Covington PTE

1.000

Annual Usage:	**585825**
sterilizer removal efficiency(%):	**0.991**
product absorption:	**0.020**
offgas during xfer to aeration	**0.00511**
offgas during aeration:	**0.649**
offgas during aeration unload:	**0.005**
RTO efficiency Aeration:	**0.990**
RTO efficiency vessels:	**0.990**

$1 - e^{-(k)(t)}$

Aeration	
0.649	lb/hr
17 hrs	
0.030	=.5hr unload

offgas during Xfer to aeration
0.0051

EO absorbed by product:	11,716.5
Sterilizer	
EO in sterilizer not absorbed by product:	574,108.5
EO Accidental release	0.0
EO exhausted to RTO from vac/air wash:	568,941.5
EO exhausted to RTO from vent:	5,167.0
Total exhaust to RTO:	574,108.5
EO removed by RTO:	568,367.4
Aeration	
EO offgas during product transfer to aeration	59.9

EOremaining in product entering aeration:			11,656.6					
EO offgas during aeration:			7,559.8		0.0	7,559.8		
misc fugitive loss:			100.0					
To RTO during aeration:			7,439.4					
To RTO during Aeration unload :			20.4					
Total aeration to RTO:			7,459.8					
aeration scrubbed:			7,385.2					
EO exhausted to atmosphere from RTO			5,815.7					
EO remaining in product:			4,096.8					
SUMMARY:								
Total EO used:			**585,825.0**					
Total removed by RTO:								
Sterilizer exhaust:			568,367.4					
Aeration exhaust:			7,385.2					
			575,752.6					
Amount exhausted to atmosphere uncontrolled:								
Sterilizer exhaust:			5,741.1					
aeration exhaust:			74.6					
xfer to aeration:			59.9					
Misc. Fugitive:			100.0					
			5,975.6					
Balance:								
	RTO Controlled		Uncontrolled		In Product			
585825 =	575,752.6	+	5,975.6	+	4,096.8			
585825 =	585,825.0							
Total released	10,072.4	lbs	5.0	tons				

C.R. Bard Covington Sterilization Air Permit Renewal 2009
AP-42 Calculations Boilers/Heaters

Data input is in the yellow boxes

Heat Input Rating 54.25 MMBTU/hr

Natural Gas Heat Content 1020 BTU/cf
Natural Gas Usage Limit 8760 hr/yr (No Limit)

Potential Emissions - Natural Gas (These emission factors are for small boilers <100MMBTU/hr)

Pollutant		Emission Factor	Reference	Emission (TPY)
Criteria Pollutants				
NOx		100 lb/10^6 scf	Table 1.4-1	23.30
CO		84 lb/10^6 scf	Table 1.4-1	19.57
PM		7.6 lb/10^6 scf	Table 1.4-2	1.77
SO_2		0.6 lb/10^6 scf	Table 1.4-2	0.14
VOC		5.5 lb/10^6 scf	Table 1.4-2	1.28
Lead		0.0005 lb/10^6 scf	Table 1.4-2	0.00
HAP				
91-57-6	2-Methylnaphthalene	2.40E-05 lb/10^6 scf	Table 1.4-3	0.00
56-49-5	3-Methylchloranthrene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
	7,12-Dimethylbenz(a)anthra	1.60E-05 lb/10^6 scf	Table 1.4-3	0.00
83-32-9	Acenaphthene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
203-96-8	Acenaphthylene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
120-12-7	Anthracene	2.40E-06 lb/10^6 scf	Table 1.4-3	0.00
56-55-3	Benz(a)anthracene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
71-43-2	Benzene	2.10E-03 lb/10^6 scf	Table 1.4-3	0.00
50-32-8	Benzo(a)pyrene	1.20E-06 lb/10^6 scf	Table 1.4-3	0.00
205-99-2	Benzo(b)fluoranthene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
191-24-2	Benzo(g,h,i)perylene	1.20E-06 lb/10^6 scf	Table 1.4-3	0.00
205-82-3	Benzo(k)fluoranthene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
218-01-9	Chrysene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
53-70-3	Dibenzo(a,h)anthracene	1.20E-06 lb/10^6 scf	Table 1.4-3	0.00
25321-22-6	Dichlorobenzeneb	1.20E-03 lb/10^6 scf	Table 1.4-3	0.00
206-44-0	Fluoranthene	3.00E-06 lb/10^6 scf	Table 1.4-3	0.00
86-73-7	Fluorene	2.80E-06 lb/10^6 scf	Table 1.4-3	0.00
50-00-0	Formaldehyde	7.50E-02 lb/10^6 scf	Table 1.4-3	0.02
110-54-3	Hexane	1.80E+00 lb/10^6 scf	Table 1.4-3	0.42
193-39-5	Indeno(1,2,3-cd)pyrene	1.80E-06 lb/10^6 scf	Table 1.4-3	0.00
91-20-3	Naphthalene	6.10E-04 lb/10^6 scf	Table 1.4-3	0.00
85-01-8	Phenanathrene	1.70E-05 lb/10^6 scf	Table 1.4-3	0.00
129-00-0	Pyrene	5.00E-06 lb/10^6 scf	Table 1.4-3	0.00
108-88-3	Toluene	3.40E-03 lb/10^6 scf	Table 1.4-3	0.00
7440-38-2	Arsenic	2.00E-04 lb/10^6 scf	Table 1.4-4	0.00
7440-41-7	Beryllium	1.20E-05 lb/10^6 scf	Table 1.4-4	0.00
7440-43-9	Cadmium	1.10E-03 lb/10^6 scf	Table 1.4-4	0.00
7440-47-3	Chromium	1.40E-03 lb/10^6 scf	Table 1.4-4	0.00
7440-48-4	Cobalt	8.40E-05 lb/10^6 scf	Table 1.4-4	0.00
7439-96-5	Manganese	3.80E-04 lb/10^6 scf	Table 1.4-4	0.00
7439-97-6	Mercury	2.60E-04 lb/10^6 scf	Table 1.4-4	0.00
7440-02-0	Nickel	2.10E-03 lb/10^6 scf	Table 1.4-4	0.00
7782-49-2	Selenium	2.40E-05 lb/10^6 scf	Table 1.4-4	0.00
			Total HAP	0.44

COVINGTON STERILIZATION GENERATORS

Fuel: Diesel — Engine Output: 1,865 hp

Sulfur Content (%) = 0.50 — Electrical Output[1]: 1,252 kilowatt

Heat Content (Btu/gal) 137,000 — Max. Fuel Input[2]: 95.3 gal/hr

Pollutant		Emission Factor	E.F. Unit	Emission Factor Source[3]	Emission Rate (lb/hr)	Emissions (ton/yr)[5]
PM		7.0E-04	lb/hp-hr	Table 3.4-1	1.31	0.33
PM_{10}		7.0E-04	lb/hp-hr	Table 3.4-1	1.31	0.33
SO_x		4.05E-03	lb/hp-hr	Table 3.4-1	7.54	1.89
NO_x		0.024	lb/hp-hr	Table 3.4-1	44.76	11.19
CO		5.50E-03	lb/hp-hr	Table 3.4-1	10.26	2.56
VOC[4]		6.42E-04	lb/hp-hr	Table 3.4-1	1.20	0.30
Total HAPs		1.57E-03	lb/MMBtu	Table 3.4-3	2.93	0.73

[1] Applicable for electrical generator sets, estimated by the equation kW = (hp) * (0.746 kW/hp) * (90% efficiency)

[2] Estimated using an average Brake Specific Fuel Consumption (BSFC) of 7,000 Btu/hp-hr

[3] AP-42 Section 3.4 - Large Stationary Diesel & Dual Fuel Engines (10/96)

[4] VOC expressed as total non-methane organic compounds (91% ot TOC)

[5] Based on 500 hs. Operation per year. Ref.:EPA Memorandum; Calculating PTE for Emergency Generators, 10/6/95

COVINGTON PLANT EMERGENCY GENERATORS

Fuel: Natural Gas — Fuel Input: 2226 scf/hr; 2.3 MMBtu/hr

Pollutant	Emission Factor (lb/MMBtu)	Emission Factor Source	Emission Rate (lb/hr)	Emissions (ton/yr)[1]
PM	0.048	Table 3.2-1	0.11	0.03
PM_{10}	0.048	Table 3.2-1	0.11	0.03
SO_x	5.88E-04	Table 3.2-1	0.001	0.00
NO_x	4.08	Table 3.2-2	9.26	2.32
CO	3.72	Table 3.2-3	8.45	2.11
VOC	0.12	Table 3.2-1	0.27	0.07
Individual HAP (formaldehyde)	0.055	Table 3.2-1	0.12	0.03
Total HAPs	0.08	Table 3.2-1	0.18	0.05

Using worst-case emission factors from AP-42 Tables for 2-stroke LB, 4-stroke LB, and 4-stroke RB (07/00)

[1] Based on 500 hs. Operation per year. Ref.:EPA Memorandum; Calculating PTE for Emergency Generators, 10/6/95

C.R. Bard Covington Sterilization Air Permit Renewal 2009
Fuel Burning Equipment

Natural Gas

COV Sterilization					
	btu/hr input	qty	tot input		
Boiler	6276000	2	12552000		
RTO Burner	7500000	2	15000000		
AT Units	4375000	2	8750000		
MAU	1600000	1	1600000		
GUH	100000	3	300000		
IR	67	3	201		
COV Plant					
Boilers	4186000	2	8372000		
H2O Heater	500000	1	500000		
RTU	166000	17	2822000		
GUH	100000	22	2200000		
IR	90000	24	2160000		
tot			54256201	54.2562	MMBTUH

Plant Emergency Generators

	Cu ft/hr	btu/hr input		
GEN 359	159	162180		
GEN 360	420	428400		
GEN 364	1647	1679940		
tot	2226	2270520	2.27052	MMBTUH

Diesel

Sterilization Emergency Generator

HP	KW	Gal/hr[1]
1818	1250	93

[1] @ 100% load

From: Amy Young
To: John LaMontagne
Date: 11/20/2009 8:56 AM
Subject: RE: Application No. 18737

John,

Your request is granted to submit the requested information and modeling by 12/31/09. Please estimate PTE from these engines and add to the facility-wide estimate. You may include engine info with 12/31/09 submittal.

Amy Young
Environmental Engineer
GA Dept. of Natural Resources
EPD Air Protection Branch
Stationary Source Permitting Program
4244 International Pkwy, Suite 120
Atlanta, GA 30354
Phone: 404-362-4844
Fax: 404-363-7100

>>> "LaMontagne, John" <John.LaMontagne@crbard.com> 11/19/2009 5:12 PM >>>
Amy,

I believe the two gasoline engines you asked about are:

Portable welder, 18 Hp engine, used approx 12 hrs per year for repair work.
Pressure washer, 9 Hp engine, used approx 20 hrs. per year for misc. cleaning activities.

Please let me know if you need additional information on these.

Also, per our discussion we would request to have until 12/31/09 to complete the requested modeling and to submit the permit information for the additional equipment.

Please let me know if this is acceptable.

Thank you,

John LaMontagne
Process Technology Engineer
Bard Medical Division

(770)784-6186

-----Original Message-----
From: Amy Young [mailto:Amy.Young@dnr.state.ga.us]
Sent: November 10, 2009 4:15 PM
To: LaMontagne, John
Subject: Application No. 18737

John,

This is to summarize our conversation of today regarding Application No. 18737 for a synthetic minor permit. It is my understanding that you would like to submit a SIP application around the timeframe of December 11, 2009 for a future sterilizer that would be processed concurrently with the synthetic minor permit. At the same time you will need to have the synthetic minor application (# 18737) updated to include the proposed equipment. Finally, I have sent you a copy of modeling done previously for the facility. It appears fugitive Ethylene Oxide

emissions were not modeled. These will need to be accounted for in a revised Toxic Impact Assessment including modeling. Also, for the proposed equipment you wish to be permitted, this will need to be modeled as well. It is acceptable to submit all of the above items by December 11, 2009.

Sincerely,

Amy Young
Environmental Engineer
GA Dept. of Natural Resources
EPD Air Protection Branch
Stationary Source Permitting Program
4244 International Pkwy, Suite 120
Atlanta, GA 30354
Phone: 404-362-4844
Fax: 404-363-7100

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

BARD

March 15, 2010

Amy Young
Environmental Engineer
Georgia Department of Natural Resources
Environmental Protection Division
Air Protection Branch
4244 International Parkway, Suite 120
Atlanta, Georgia 30354-3908

Dear Ms. Young:

RE: Draft Permit No. 3841-217-0021-S-03-0

Thank you for the opportunity to comment on the revised permit. Below are our comments based on the draft you sent on March 5, 2010.

Permit Section:

2.5 The emission limitations of Condition Nos. 2.3. and 2.4 apply during sterilization operation. The emission limits do not apply during periods of malfunction.
[40 CFR 63 Subpart O; 40 CFR 63.362(b)]

Change last sentence to:

The emission limits do not apply during periods of malfunction or when Ethylene Oxide emissions are not present.

Rationale:

There are times when the sterilization process is in operation but emissions are not present at the emission control device. Revising as indicated above will clarify that the conditions are only applicable when processing emissions.

Permit Section:

5.1 The Permittee shall either continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition 5.2 or measure and record the ethylene oxide concentration in accordance with §63.364(e). Monitoring is required only when the Regenerative Thermal Oxidizer (RTO-1) is operated.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)]

From: Amy Young
To: John.LaMontagne@crbard.com
Date: 3/18/2010 1:46 PM
Subject: RE: Bard Medical Division, Covington

John,

We have reviewed your comments. With regards to Conditions 2.5 and 5.1 through 5.3, because the language is directly from the MACT standard, we cannot change it. With regards to a replacement temperature sensor, any replacement sensor would still be subject to Condition 5.3 as written. With regards to testing, testing is required 180 days after initial startup of the new equipment pursuant to 40 CFR 63.363(a). For specific questions regarding testing requirements, you may contact our ISMP program. For specific questions regarding compliance, you may contact your compliance engineer. We intend to issue the permit shortly. If you have any questions or concerns, please contact me at 404-362-4844 or at amy.young@dnr.state.ga.us.

Thank you

Amy Young
Environmental Engineer
GA Dept. of Natural Resources
EPD Air Protection Branch
Stationary Source Permitting Program
4244 International Pkwy, Suite 120
Atlanta, GA 30354
Phone: 404-362-4844
Fax: 404-363-7100

>>> "LaMontagne, John" <John.LaMontagne@crbard.com> 03/15/10 4:54 PM >>>
Amy,

Our comments are attached. I will also send a copy via mail.

Call me (770)784-6186 if questions.

John

-----Original Message-----
From: Amy Young [mailto:Amy.Young@dnr.state.ga.us]
Sent: March 05, 2010 2:25 PM
To: LaMontagne, John
Subject: Bard Medical Division, Covington

John,

Hi. Attached is the draft synthetic minor permit for the Covington facility. Please have any comments back by COB March 12, 2010. Thank you.

Amy Young
Environmental Engineer
GA Dept. of Natural Resources
EPD Air Protection Branch
Stationary Source Permitting Program
4244 International Pkwy, Suite 120
Atlanta, GA 30354
Phone: 404-362-4844
Fax: 404-363-7100

ack

From: Amy Young
To: John.LaMontagne@crbard.com
Date: 2/18/2010 9:48 AM
Subject: GA Air Application: 19408 dated: 30-Dec-2009

Dear Mr. LaMontagne,

This is to acknowledge the receipt of your GA Air Quality Permit application for Bard C R Inc Urologic (Airs No. 21700021) in Covington, GA. After our initial review of the information and technical data in this application, we will notify you if more information is needed to complete the application so that we can finish our review.

If your company qualifies as a small business (generally those with less than 100 employees), you may contact our Small Business Environmental Assistance Program at 404/362-4842 for free and confidential permitting assistance.

To track the status of the air quality permit application, log on to Georgia Environmental Protection Division's Georgia Environmental Connections Online (GECO) at the web address http://airpermit.dnr.state.ga.us (registration required) and follow the online instructions.

If you have any questions or concerns regarding your application, please contact me at (404) 362-4844 or via e-mail at amy.young@dnr.state.ga.us. Any written correspondence should reference the above application number that has been assigned to this application and the facility's AIRS number.

State of Georgia
Department of Natural Resources
Environmental Protection Division
Air Protection Branch

Stationary Source Permitting Program
4244 International Parkway, Suite 120
Atlanta, Georgia 30354
404/363-7000
Fax: 404/363-7100

SIP AIR PERMIT APPLICATION

EPD Use Only

Date Received: _____ Application No. _____

FORM 1.00: GENERAL INFORMATION

1. Facility Information

Facility Name: Bard Medical Division, Covington

AIRS No. (if known): 04-13- 217 - 00021

Facility Location: Street: 8195 Industrial Blvd

City: Covington Georgia Zip: 30014 County: Newton

2. Facility Coordinates

Latitude: 33° 36' 42" **NORTH** Longitude: 83° 50' 17" **WEST**

UTM Coordinates: _____ **EAST** _____ **NORTH** **ZONE** _____

3. Facility Owner

Name of Owner: C.R. Bard Incorporated

Owner Address Street: 730 Central Avenue

City: Murry Hill State: NJ Zip: 07974

4. Permitting Contact and Mailing Address

Contact Person: John LaMontagne Title: Process Technology Engineer

Telephone No.: 770 784 6186 Ext. _____ Fax No.: 770 788 5519

Email Address: john.lamontagne@crbard.com

Mailing Address: Same as: Facility Location: ☒ Owner Address: ☐ Other: ☐

If Other: Street Address: _____

City: _____ State: _____ Zip: _____

5. Authorized Official

Name: Mary S. Mayo Title: Staff VP Quality Assurance

Address of Official Street: 8195 Industrial Blvd.

City: Covington State: GA Zip: 30014

This application is submitted in accordance with the provisions of the Georgia Rules for Air Quality Control and, to the best of my knowledge, is complete and correct.

Signature: for M. Mayo
Brian R. Drumheller

Date: 12/30/09

6. **Reason for Application: (Check all that apply)**

☐ New Facility (to be constructed)

☒ Existing Facility (initial or modification application)

☒ Permit to Construct

☒ Permit to Operate

☐ Change of Location

☐ Permit to Modify Existing Equipment: Affected Permit No.: _____

☐ Revision of Data Submitted in an Earlier Application

Application No.: _____

Date of Original Submittal: _____

7. **Permitting Exemption Activities (for permitted facilities only):**

Have any exempt modifications based on emission level per Georgia Rule 391-3-1-.03(6)(i)(3) been performed at the facility that have not been previously incorporated in a permit?

☒ **No** ☐ **Yes, please fill out the SIP Exemption Attachment** (See Instructions for the attachment download)

8. **Has assistance been provided to you for any part of this application?**

☐ **No** ☐ **Yes, SBAP** ☒ **Yes, a consultant has been employed or will be employed.**

If yes, please provide the following information:

Name of Consulting Company: Trinity Consultants

Name of Contact: John Wilcox

Telephone No.: 678 441 9977 Fax No.: _____

Email Address: _____

Mailing Address: Street: 53 Perimeter Center East

City: Atlanta State: ga Zip: 30346

Describe the Consultant's Involvement:

Completed Toxic Impact Assessment

9. **Submitted Application Forms:** Select only the necessary forms for the facility application that will be submitted.

No. of Forms	Form
1	2.00 Emission Unit List
	2.01 Boilers and Fuel Burning Equipment
	2.02 Storage Tank Physical Data
	2.03 Printing Operations
	2.04 Surface Coating Operations
	2.05 Waste Incinerators (solid/liquid waste destruction)
1	2.06 Manufacturing and Operational Data
	3.00 Air Pollution Control Devices (APCD)
	3.01 Scrubbers
	3.02 Baghouses & Other Filter Collectors
	3.03 Electrostatic Precipitators
1	4.00 Emissions Data
1	5.00 Monitoring Information
1	6.00 Fugitive Emission Sources
1	7.00 Air Modeling Information

10. **Construction or Modification Date**

Estimated Start Date: 2011

11. If confidential information is being submitted in this application, were the guidelines followed in the "Procedures for Requesting that Submitted Information be treated as Confidential"?

☐ No ☐ Yes

12. New Facility Emissions Summary

Criteria Pollutant	New Facility	
	Potential (tpy)	Actual (tpy)
Carbon monoxide (CO)	n/a	n/a
Nitrogen oxides (NOx)	n/a	n/a
Particulate Matter (PM)	n/a	n/a
PM <10 microns (PM10)	n/a	n/a
PM <2.5 microns (PM2.5)	n/a	n/a
Sulfur dioxide (SO_2)	n/a	n/a
Volatile Organic Compounds (VOC)	n/a	n/a
Total Hazardous Air Pollutants (HAPs)	n/a	n/a
Individual HAPs Listed Below:		
n/a	n/a	n/a

13. Existing Facility Emissions Summary

Criteria Pollutant	Current Facility		After Modification	
	Potential (tpy)	Actual (tpy)	Potential (tpy)	Actual (tpy)
Carbon monoxide (CO)	n/a	n/a	n/a	n/a
Nitrogen oxides (NOx)	n/a	n/a	n/a	n/a
Particulate Matter (PM)	n/a	n/a	n/a	n/a
PM <10 microns (PM10)	n/a	n/a	n/a	n/a
PM <2.5 microns (PM2.5)	n/a	n/a	n/a	n/a
Sulfur dioxide (SO_2)	n/a	n/a	n/a	n/a
Volatile Organic Compounds (VOC)	n/a	n/a	n/a	n/a
Total Hazardous Air Pollutants (HAPs)	n/a	n/a	n/a	n/a
Individual HAPs Listed Below:				
Ethylene Oxide	3.9	2.9	5.0	TBD

14. 4-Digit Facility Identification Code:

SIC Code: 3841 SIC Description: SURGICAL & MEDICAL INSTRUMENTS & APPARATUS

NAICS Code: 339112 NAICS Description: Surgical and Medical Instrument Manufacturing

15. Description of general production process and operation for which a permit is being requested. If necessary, attach additional sheets to give an adequate description. Include layout drawings, as necessary, to describe each process. References should be made to source codes used in the application.

This modification adds one process line to an existing facility. The Facility was constructed to facilitate an additional sterilization line. The origional application did not include the aditional emission units as there are no immidiate plans to install the equipment. Equipment is being added at this time as we are in the permit renewal process and want to avoid additional permiting activity in the event it is decided to install the additional equipment.

Additional process line includes:

SV5 Sterilization Chamber #5
A5A Aeration Cell 5A
A5B Aeration Cell 5B

16. Additional information provided in attachments as listed below:

Attachment A - Plant layout showing location of additional equipment

Attachment B - Batch Summary as referenced in Form 2.06

Attachment C -

Attachment D -

Attachment E -

Attachment F -

17. Additional Information: Unless previously submitted, include the following two items:

☐ Plot plan/map of facility location or date of previous submittal: 2003

☐ Flow Diagram or date of previous submittal: 2003

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 2.00 – EMISSION UNIT LIST

Emission Unit ID	Name	Manufacturer and Model Number	Description
SV5	Sterilization Vessel #5	TBD	Medical Divice Sterilization Chamber
A5a	Aeration Cell 5A	TBD	Post sterilization aeration cell
A5b	Aeration Cell 5B	TBD	Post Sterilization Aeration cell

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 2.06 – MANUFACTURING AND OPERATIONAL DATA

Normal Operating Schedule: 24 hours/day 7 days/week 52 weeks/yr

Additional Data Attached? ☐ - No ☒ - Yes, please include the attachment in list on Form 1.00, Item 16.

Seasonal and/or Peak Operating Periods: n/a

Dates of Annually Occurring Shutdowns: Typically January (4 days)

PRODUCTION INPUT FACTORS

Emission Unit ID	Emission Unit Name	Const. Date	Input Raw Material(s)	Annual Input	Hourly Process Input Rate		
					Design	Normal	Maximum
SV5	Sterilization Chamber #5	TBD	See Batch Summary	See Summary			
A5A	Aeration Cell 5A	TBD	See Batch Summary	See Summary			
A5B	Aeration Cell 5B	TBD	See Batch Summary	See Summary			

PRODUCTS OF MANUFACTURING

Emission Unit ID	Description of Product	Production Schedule		Hourly Production Rate (Give units: e.g. lb/hr, ton/hr)			
		Tons/yr	Hr/yr	Design	Normal	Maximum	Units
SV5	Pallets of Medical Devices	See Batch Summary					
A5A	Pallets of Medical Devices	See Batch Summary					
A5B	Pallets of Medical Devices	See Batch Summary					

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 4.00 – EMISSION INFORMATION

Emission Unit ID	Air Pollution Control Device ID	Stack ID	Pollutant Emitted	Emission Rates				
				Hourly Actual Emissions (lb/hr)	Hourly Potential Emissions (lb/hr)	Actual Annual Emission (tpy)	Potential Annual Emission (tpy)	Method of Determination
SV5	RTO1	RTOa	Ethylene Oxide	TBD	.2	TBD	.7	Mass Balance
A5a	RTO1	RTOa	Ethylene Oxide	TBD	.001	TBD	.006	Mass Balance
A5b	RTO1	RTOa	Ethylene Oxide	TBD	.001	TBD	.003	Mass Balance

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 5.00 MONITORING INFORMATION

Emission Unit ID/ APCD ID	Emission Unit/APCD Name	Monitored Parameter		Monitoring Frequency
		Parameter	Units	
RTO1	Regenerative Thermal Oxidizer	Temperature	F	Continuous

Comments:

Facility Name: Bard Medical Division **Date of Application:** 12/20/09

FORM 6.00 – FUGITIVE EMISSION SOURCES

Fugitive Emission Source ID	Description of Source	Emission Reduction Precautions	Pot. Fugitive Emissions	
			Amount (tpy)	Pollutant
STOR1	Sterilized Product Storage	Product Aeration	.5	Ethylene Oxide
FUG1	Transfer from Vessel to Aeration	Automated Euipment	.007	Ethylene Oxide

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 7.00 – AIR MODELING INFORMATION: Stack Data

Stack ID	Emission Unit ID(s)	Stack Information			Dimensions of largest Structure Near Stack		Exit Gas Conditions at Maximum Emission Rate			
		Height Above Grade (ft)	Inside Diameter (ft)	Exhaust Direction	Height (ft)	Longest Side (ft)	Velocity (ft/sec)	Temperature (°F)	Flow Rate (acfm)	
									Average	Maximum
RTOa	RTO1	50	4	Towards the Sky	n/a	n/a	30.5	440	TBD	29692

NOTE: If emissions are not vented through a stack, describe point of discharge below and, if necessary, include an attachment. List the attachment in Form 1.00 *General Information*, Item 16.

Facility Name: Bard Medical Division, Covington **Date of Application:** 12/20/09

FORM 7.00 AIR MODELING INFORMATION: Chemicals Data

Chemical	Potential Emission Rate (lb/hr)	Toxicity	Reference	MSDS Attached
Ethylene Oxide	.27	OSHA PEL (8 HR. TWA): 1 ppm OSHA 15 MINUTE EXCURSION LIMIT: 5 ppm; 9 mg/m3 ACGIH TLV/TWA: 1 ppm; 1.8 mg/m3 IDLH: 800 ppm	OSHA PELs, ACGIH TLVs	☐
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Batch Calculation Summary for SIP Form 2.06

Bard Medical Division, Covington

Days of Operation	365
Hours of Operation	8760
Bacth time (minimum)	
SV5 (hrs.)	8
A5A (hrs)	8
A5B (hrs.)	8

24 Pallets are sterilized in SV5, then are moved to Aeration Cell A5A, then moved to A5B

Batch summary is estimated based on design maximum

SV5 Batch Summary	
Batches/year	1095
Pallets/batch	24
Pallets/year input	26280
lbs. Ethylene Oxide/batch	125
lbs. Ethylene/year input	136875
Pallets/year output	26280

A5A Batch Summary	
Batches/year	1095
Pallets/batch	24
Pallets/year input	26280
Pallets/year output	26280

A5B Batch Summary	
Batches/year	1095
Pallets/batch	24
Pallets/year input	26280
Pallets/year output	26280